

Vaccine Loss and Replacement Protocol

Missouri Vaccines for Children Program

*****POST IN A CONSPICUOUS PLACE*****

Definitions

Wasted:	<i>Any vaccine that cannot be used. This includes expired, non-viable and lost vaccines.</i>
Expired:	<i>Any vaccine with an expiration date that has passed.</i>
Non-viable:	<i>Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. <u>Always</u> consult VFC Program before determining the vaccine is non-viable.</i>
Lost:	<i>UPS, FedEx, or other delivery service does not deliver the vaccine or does not deliver in a timely manner.</i>
Abuse:	<i>Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.</i>
Fraud:	<i>An intentional deception, or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person</i>

This document will serve as the Missouri Department of Health and Senior Services protocol for management of incidents that result in loss of vaccine supplied by Missouri Vaccines for Children (VFC) Program. The action taken by the VFC Program will depend on the category of the vaccine loss. For the purpose of this document, wasted vaccines fall under three categories:

Category 1 – Non-Preventable Loss

Category 2 – Non-Compliance

Category 3 – Negligence

Note: In the event that children may have been vaccinated with expired or otherwise non-viable vaccine, the VFC program staff will provide guidance to clinic staff to make appropriate re-vaccination plans.

Standard Plan of Action for Vaccine Loss

Provider is to contact the VFC Program at **(800) 219-3224** and the vaccine manufacturer(s) as soon as the situation is discovered and explain the circumstances to the representatives. Be prepared to furnish the following information:

- Last known temperature of the refrigerator/freezer and the date and time of that reading;
- Current temperature of the refrigerator/freezer;
- Duration of time the vaccines were stored out of recommended temperature range, lot numbers and expiration dates of all vaccines in question, number of doses, and manufacturer.

Provider will submit written strategies to prevent future misuse/abuse of VFC vaccine to the VFC Program.

If the vaccines are determined to be viable, but the power to the office has not been restored or the refrigerator is still in disrepair, the provider must enact their Vaccine Emergency Plan. Vaccines must be transported immediately to an alternate refrigerator/freezer.

Category 1 – Non-Preventable Loss

Vaccine loss due to non-preventable circumstances, such as:

- Area power outages due to severe weather or other unavoidable and unanticipated causes.
- Refrigerator/freezer failure – unavoidable or unanticipated. (Refer to your refrigerator manufacturers manual and CDC's Vaccine Storage and Handling toolkit at: <http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html>)
- Transport company error (i.e., FedEx, UPS, etc.).

*****Note: Failure of the provider to notify VFC of a change in office hours or address will not be considered a transport company error. *****

If the vaccines in question are not salvageable, the VFC program staff will advise the provider concerning return of the wasted vaccines. As soon as power is restored, the provider should monitor and provide the VFC office with temperature logs for 3 days. If the refrigerator or freezer has been replaced, notify the VFC Program so that a program representative can certify the refrigerator/freezer. A determination will be made when replacement vaccines will be shipped to the provider.

Category 2 – Vaccine Loss Due to Non-Compliance

Vaccine loss due to non-compliance is defined as:

1. VFC vaccine not accounted for per VFC Program requirements.
Examples include, but are not limited to:
 - Failure to document doses administered on usage log;
 - Failure to document patient eligibility on usage log;
 - Failure to report inventory;
 - Inaccurate reporting of inventory;
 - Failure to report expired/wasted vaccine.
2. VFC vaccine knowingly administered to children who do not meet VFC Program eligibility criteria.
3. Accepting reimbursement from insurance companies or patients for VFC vaccine as evidenced by:
 - Administering VFC vaccine to a child and subsequently billing the child's insurance for the cost of the vaccine;
 - Charging the patient for the cost of the vaccine;
 - Charging a Medicaid recipient any fee at all.

Additional Plan of Action for Non-Compliance wastage:

If a provider is found to be in violation of written VFC policies, the action taken will depend upon the policy violated as follows:

1. Vaccine unaccounted for in usage reports.

- The provider must report vaccine usage and inventory to the VFC Program per VFC Program guidelines. Follow-up visits by VFC program representatives will be conducted as determined by VFC Program.
- The provider must develop strategies to reduce vaccine loss, which may include, but are not limited to the following:
 - Vaccine medication log;
 - Accountability on weekly basis;
 - Rotation of staff responsible for vaccine accountability;
 - Review intake sheets.

******Note: Upon receipt of written notification from the provider, any infractions or continued administration of VFC supplied vaccine to children not eligible for VFC will result in decreased vaccine shipments, suspension or termination from the VFC Program.******

2. Knowingly administering VFC vaccine to children who do not meet VFC Program eligibility criteria, accepting reimbursement from insurance companies or charging patients for VFC supplied vaccine is paramount to fraud and/or abuse.

******Note: Fraud and abuse cases will be forwarded to the appropriate authorities for investigation and potential prosecution.******

The VFC Program may require additional information including, but not limited to:

- VFC eligibility screening records;
- Medicaid billing records;
- Tally records.

Category 3 – Negligence

Negligence is defined as loss of vaccine on the part of the provider/clinic staff. The following situations qualify in this category:

1. Vaccine stored improperly (i.e., refrigerating vaccine that should have been frozen, vaccine left out of freezer or refrigerator, or freezing vaccine that should have been refrigerated).
2. Refrigerator or freezer unplugged or electrical service interrupted (circuit breaker).
3. Door of refrigerator or freezer left ajar resulting in unit temperatures outside the acceptable range.

4. Improper maintenance of recommended refrigerator and freezer temperatures.
5. Failure to properly read and record refrigerator(s) and freezer(s) temperatures, and/or take immediate corrective actions when temperatures are out of appropriate range.
6. Failure to properly train back-up personnel on storage and handling protocol.
7. Pre-drawing or pre-mixing vaccine, then not administering in accordance with vaccine manufacturer/CDC recommendations.
8. Transporting vaccine inappropriately (not using ice packs or dry ice), thus not maintaining the cold chain.
9. Failure to notify the VFC Program when provider office hours change or the practice moves, resulting in vaccines being undeliverable and consequently becoming non-viable.
10. Vaccine expired due to failure of the provider to notify the VFC Program three months prior to expiration date so that vaccine could be transferred; and/or
11. Failure to rotate stock appropriately.

Additional Plan of Action for Negligence Wastage:

The VFC program staff will determine disposition of non-viable vaccine. The provider may be required to purchase replacement vaccines, if it is determined that the loss was due to provider negligence.

When replacement of vaccine is required:

1. The provider will submit to the VFC Program a written report of the incident within 10 business days that describes the circumstances and the steps taken to ensure that vaccine is protected in the future.
2. The provider must mail or fax invoices for replacement vaccine to the VFC Program within 10 business days after receipt of replacement vaccine.
3. When revaccination of children is necessary, the provider must prepare and submit to the VFC Program a listing of all children needing revaccination within 10 business days.
4. The assigned VFC program representative will verify by site visit, the replacement of the vaccines and documentation of revaccination of all affected children within 30 days of incident.
5. The assigned VFC field representative will conduct a follow-up visit within 3 months of the incident to monitor vaccine storage and handling policies.
6. Any vaccine that is deemed wasted must be returned to the VFC Program at the provider's expense. This vaccine will be returned to the manufacturer for excise tax credit for purchase of additional vaccines.

When replacement of vaccine is not required:

1. The provider will submit to the VFC Program a written report of the incident within 10 business days that describes the circumstances and the steps taken to ensure that vaccine is protected in the future.

2. Vaccine shipments will be resumed upon receipt of the aforementioned letter. The assigned VFC field representative will conduct a follow-up visit within 3 months of the incident to monitor vaccine storage and handling policies.
3. Any vaccine that is deemed not usable due to negligent circumstances should be returned to the VFC Program at the provider's expense. This vaccine will be returned to the manufacturer for excise tax credit for purchase of additional vaccines.

I have read the Missouri Vaccines for Children Vaccine Loss and Replacement Protocol

(Please print)

Provider Name: _____ **Provider #** _____

Address: _____

Telephone: _____ **Fax:** _____

Signature: _____ **Date:** _____

Sign and return to Missouri VFC Program

Fax to: 800-219-3224

Or mail to: VFC Program

Missouri Department of Health & Senior Services
930 Wildwood Dr., P.O. Box 570
Jefferson City, Missouri 65102-0570